REMARKS

The instant application is related in part to apparatuses and kits that utilize one or more assay controls for monitoring the performance of assays. Such controls provide a measurable signal that is generated in connection with, but that is independent of, a signal obtained from the assay for an analyte of interest, typically through the use of members of a binding pair that do not bind to any analyte(s) targets for detection by the assay device, or to any assay reagents used to detect such analyte(s). In particular, the instant claims relate to apparatuses and kits that use an assay control for measuring the progress and time of completion of an assay.

Claims 27-28 and 93-108 are pending in the instant application, with claims 6-7, 16-17, 29-47 and 54-92 having being cancelled by the Applicants. Claims 27 and 28 are amended herein. The amended claims are fully supported by the specification and do not introduce new matter or require a new search. The amendment simply clarifies the claimed invention using preferred terminology, and are not intended to further limit the claims, and should not be taken to do so. Specific support for devices comprising both assay zones and timing zones can be found in the specification, *e.g.*, on page 70, lines 4-13.

Notwithstanding the foregoing, Applicants expressly reserve the right to prosecute subject matter no longer or not yet claimed in one or more applications that may claim priority hereto. Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the following comments.

Non-Art Related Remarks

Priority:

Applicants respectfully submit that the specification has been amended herein to reflect the appropriate priority claim.

Information Disclosure Statement:

The Examiner indicated that the Information Disclosure Statement submitted by Applicants was not considered because it was not signed. Applicants note that, with the exception of two publications, each item listed in the Information Disclosure Statement was submitted in the parent application, and should, therefore, be considered by the Examiner in the instant application. Applicants submit herewith the remaining two publications in a new Information Disclosure Statement, and respectfully request that each be considered by the Examiner.

Drawings:

Applicants respectfully submit corrected formal drawings herewith.

Specification:

A clean copy of the amended specification, containing no new matter relative to that originally filed, is submitted herewith. The amended specification has been amended to include the appropriate priority claim by amending the first sentence of the specification to read "This application is a continuation of Application No. 09/003,065, filed on January 5, 1998, now Patent No. 6,194,222". Applicants have also corrected the improper cut off portion(s) of pages 71, 72, 78 and 88; and the patent application on page 53, line 14 has bee corrected to read "WO 96/05476".

With regard to the use of trademarks, Applicants respectfully submit that SMCC and SPDP on pages 52 and 57 are not trademarks. Rather, they are abbreviations of chemical compounds: SMCC is an abbreviation for (succinimidyl 4-[N-maleimidomethyl]cyclohexane-1-carboxylate), and SPDP is an abbreviation for (N-Succinimidyl-3-[2-pyridyldithio]propionate).

Claim Objections

Applicants have amended claims 27 and 28 to place the claims in Markush format, and have deleted the duplicate use of (a) and (b) in claim 28. Applicants respectfully submit that these amendments are not made for reasons of patentability, but merely to assist the Examiner's understanding of the claimed invention. Furthermore, these amendments to the claims do not alter the scope of the claimed invention, and should not be taken to do so.

35 USC §112, Second Paragraph

Claims 27-28 and 93-108 have been rejected under 35 USC 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter of the invention. Paper No. 7, page 6. Applicants respectfully traverse this rejection.

When determining definiteness, the proper standard to be applied is "whether one skilled in the art would understand the bounds of the claim when read in the light of the specification." *Credle v. Bond*, 30 USPQ2d 1911, 1919 (Fed. Cir. 1994). See also *Miles Laboratories, Inc. v. Shandon, Inc.*, 27 USPQ2d 1123, 1127 (Fed. Cir. 1993) ("If the claims read in the light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more.") (emphasis added).

"for an assay in an assay device"

Applicants respectfully disagree with the Examiner's assertion that claims 27 and 28 are allegedly vague and indefinite because it is allegedly unclear what the limitation "for an assay in an assay device" entails. The skilled artisan is well acquainted of methods and devices for performing analyte assays.

In an effort to advance prosecution, however, Applicants have amended the claims to clarify the relationship between the elements of the apparatus and the analyte assay. Thus, the claims as amended refer to an apparatus for measuring the progress and time of completion of an

assay for an analyte, in which a device comprising at least one zone adapted to bind said predetermined analyte at a detection zone.

The instant specification provides an extensive disclosure describing the use of such devices generally, and their use for measuring the progress and time of completion of an assay. *See, e.g.*, specification, page 59, line 1, through page 61, line 27. As indicated in the specification, *e.g.*, on page 40, line 1, through page 41, line 12, the label referred to in the claims may or may not be related to a label used to detect analyte immobilized on the detection zone. Furthermore, the timing zone may be configured to bind the label, or may be configured to be a region that binds no label. *See, e.g.*, specification, page 70, lines 11-13. In each case, the signal obtained from label in the timing zone is related to the flow of reagents through the device, indicating when the assay has been completed, but is not related to the presence or amount of the analyte of interest.

For example, in the exemplary embodiment on pages 69-70, the specification describes an assay device comprising a diagnostic lane with several analyte-specific detection zones that bind labeled species in an analyte-specific manner, and a timing zone that does not specifically bind any of the labeled species used in these analyte assays. The signal obtained from the timing zone is related to the amount of labeled species free in solution and the amount of labeled species that might nonspecifically bind at the timing zone. As the fluid begins to traverse the diagnostic lane, fluorescence observed from the timing zone is high, as the concentration of labeled species present in the assay fluid is high. Completion of the assay is signalled by a loss of fluorescence in the timing zone, indicating that the unbound labeled species within the device have now exited the diagnostic lane.

Applicants respectfully submit that the skilled artisan is reasonably apprised of the scope of the invention with regard to the amended claims, and that, therefore, the foregoing claim amendments render the rejection moot.

"at least one discrete zone"

The Examiner also contends that there is allegedly an insufficient antecedent basis for the limitation "at least one discrete zone" in a diagnostic lane. Applicants respectfully disagree. Inherent components of an element recited in the claims have an antecedent basis in the recitation of the element itself. See, e.g., MPEP §2173.05(g). Nevertheless, in an effort to advance prosecution, Applicants have amended the claims to refer explicitly to a diagnostic lane comprising at least one discrete zone adapted to bind the analyte of interest and at least one timing zone.

Methods for adapting a diagnostic lane to bind various components, such as by immobilizing an antibody, complementary nucleic acid, receptor, *etc.*, having a specific binding affinity for a component, are well known to the skilled artisan. Furthermore, exemplary methods for adapting a diagnostic lane to bind various molecules are described in the instant specification, e.g., on page 59, line 21, through page 60, line 13. Thus, the skilled artisan is reasonably apprised of the scope of the invention. Applicants, therefore, submit that the foregoing claim amendments render the rejection moot.

"an absolute amount" and "does not appreciably bind"

With respect to the phrase "an absolute amount" and "does not appreciably bind", Applicants respectfully submit that the foregoing amendments render the rejection moot.

"a signal generated from said label in at least one discrete zone of said diagnostic lane"

The Examiner also contends it is unclear how "a signal generated from said label in at least one discrete zone of said diagnostic lane" is detected, since the label is provided in the reaction chamber. Applicants respectfully submit that the specification as filed makes clear the relationship between the label and the diagnostic lane. For example, the label may be provided on the surface of the reaction chamber, where it is washed through the device with the sample to contact the diagnostic lane. *See, e.g.*, specification, page 36, lines 14-25. Nevertheless,

Applicants have amended the claims herein to refer explicitly to the relationship between the various elements of the device. Applicants submit that the foregoing claim amendments render the rejection moot.

The Examiner has contended that the claim 28(a) is allegedly indefinite in reciting "a Food and Drug Administration label," because such a label allegedly does not describe the apparatus, and because "FDA" is allegedly a trademark. Applicants respectfully disagree. The phrase "a Food and Drug Administration label" is well understood by the skilled artisan, and is clearly defined in the specification, e.g., on page 9, lines 23-28. Moreover, "FDA" is not a trademark, but is instead a well known abbreviation used in the art. Nevertheless, Applicants have deleted the phrase from the claims, thereby rendering the rejection moot

The Examiner has contended that claims 28 and 101-108 are allegedly being incomplete for omitting essential elements for any kit components other than the device. Applicants respectfully submit that the foregoing amendments rendering the rejection moot.

Art-Related Remarks

Double Patenting

Claims 27, 28 and 93-108 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 14-22 of U.S. Patent No. 6,194,222 ('222). Applicants respectfully traverse the rejection.

It is respectfully submitted that the instant application is a continuation of Application No. 09/003,065, now U.S. Patent No. 6,194,222. A restriction requirement was issued during the prosecution of the '222 patent. *See*, Paper No. 9, page 2 in the file history for '222 patent. The claims in the instant application are drawn to the previously non-elected Group VI claims. A double patenting rejection is not permitted where the claimed subject matter is presented in a divisional application as a result of a restriction requirement made in a parent application. *See,*

e.g., MPEP 804. Therefore, Applicants respectfully request that the Examiner withdraw the double patenting rejection.

35 U.S.C. §102

Claims 27, 93, 94, 96, 97, 98, 99 and 100 have been rejected under 35 U.S.C. §102(e), as allegedly being anticipated by Sheppard et al., U.S. Patent 6,143,247 ("the '247 patent"). Applicants respectfully traverse this rejection.

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. Furthermore, the claims must be interpreted in light of the teaching of the specification. In re Bond, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). See also MPEP §2131.

The Examiner contends that the '247 patent contains a signal processor, referring to a "detector or optical heads." Applicants respectfully submit that nothing of record indicates that these elements described in the '247 patent perform any signal processing function. Nevertheless, in an effort to advance prosecution, Applicants have amended the claims to refer to a signal processor configured to receive an electronic signal from an optical component and to determine the progress and time of completion of an assay. Because no such signal processor is disclosed in the '247 patent, no *prima facie* case of obviousness has been established.

Moreover, the Examiner is incorrect that "the claimed functional limitation [of detecting the progress and time of completion of an assay] would be [an] inherent property of the referenced device" (Paper No. 7, page 10). The mere fact that such a characteristic may occur is not sufficient to establish inherency. *See, e.g.*, MPEP §2112. Applicants respectfully request that the Examiner provide extrinsic evidence making it clear that the missing descriptive matter, *i.e.*, a signal processor configured to receive an electronic signal from an optical component and to determine the progress and time of completion of an assay, is necessarily present in the devices disclosed in the '247 patent.

Because the '247 patent does not teach and suggest every limitation of the claimed invention, the '247 patent does not anticipate the instantly claimed invention. Applicants, therefore, respectfully request that the rejection under 35 U.S.C. §102(e) be reconsidered and withdrawn.

35 U.S.C. §103(a)

Claims 27, 93, 94, 96, 97, 98, 99 and 100 have been rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Buechler et al., U.S. Patent No. 5,458,852 ("the '852 patent") in view of Van Deusen et al., US Patent No. 5,132,097 ("the '097 patent"). Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness, three criteria must be met: there must be some motivation or suggestion, either in the cited references or in knowledge available to the ordinarily skilled artisan, to modify or combine the references; there must be a reasonable expectation of success in combining the references; and the references must teach or suggest all of the claim limitations. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) See also MPEP §2143.

As discussed above, the instant claims refer to an apparatus for measuring the progress and time of completion of an assay. Moreover, Applicants have clarified the elements contained within the claimed devices by referring to a signal processor configured to receive an electronic signal from an optical component and to determine the progress and time of completion of an assay. The Examiner does not contend that the cited patents, either alone or in combination, disclose such devices.

Therefore, because the references do not teach or suggest all of the claim limitations, no *prima facie* case of obviousness has been established. Applicants, therefore, respectfully request that the rejection under 35 U.S.C. §103(a) be reconsidered and withdrawn.

The Examiner has also rejected claim 95 under 35 U.S.C. §103(a) as allegedly being unpatentable over Sheppard et al., U.S. Patent No. 6,143,247 ("the '247 patent") or Buechler,

U.S. Patent No. 5,458,852 ("the '852 patent") in view of Van Deusen et al., U.S. Patent No. 5,132,097 ("the '097 patent") in further view of Slovacek et al., U.S. Patent No. 5,424,837 ("the '837 patent"); and claims 28 and 101-108 in further view of Zuk et al., U.S. Patent No. 4,281,061 ("the '061 patent"). Applicants respectfully traverse these rejections.

For the reasons discussed above, the cited patents, alone or in combination, do not teach or suggest every claim limitation. Therefore, no *prima facie* case of obviousness has been established. Applicants, therefore, respectfully request that the rejection under 35 U.S.C. §103(a) be reconsidered and withdrawn.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable consideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date November 9, 2001

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Appendix C: Marked-up claims, indicating the amendments

27. (Amended) [A] An apparatus for measuring progress and time of completion [for] of an assay for an analyte in a fluid sample [in an assay device], comprising:

(a) [said] an assay device [including] comprising:

(i) a reaction chamber comprising a detectable label, and

(ii) at least one diagnostic lane comprising at least one zone adapted to bind said analyte and at least one timing zone, wherein said diagnostic lane is in fluid communication with said reaction chamber, and wherein, when fluid is added to said reaction chamber, said detectable label flows with said fluid to said diagnostic lane[; wherein a label is provided in said reaction chamber];

(b) an optical component for detecting an optical signal generated from said label in at least one [discrete] said timing zone of said diagnostic lane and generating an electronic signal in response;

(c) a signal processor for configured to receive said electronic signal and to determine [determining] said progress and time of completion of said assay for said analyte in said assay device from at least one parameter selected from the group consisting of[:

(i)] a rate of change of the amount of said electronic signal [;] and

[(ii)] an [absolute] amount of said electronic signal.[;

[wherein said label does not appreciably bind to any assay reagents in said assay device.]

28. (Amended) A kit for measuring progress and time of completion [for] of an assay for an analyte [in an assay device], comprising:

(a) at least one [of a Food and Drug Administration Label and a] set of instructions for measuring said progress and time of completion; and

(b) an apparatus according to claim 27.[, comprising:

(i) said assay device including a reaction chamber and at least one diagnostic lane; wherein a label is provided in said reaction chamber;

(ii) an optical component for detecting a signal generated from said label in at least one discrete zone of said diagnostic lane; and

(iii) a signal processor for determining said progress and time of completion of said assay in said assay device from at least one of:

(a) a rate of change of the amount of said signal; and

(b) an absolute amount of said signal;

wherein said label does not appreciably bind to any assay reagents in said assay device.]